



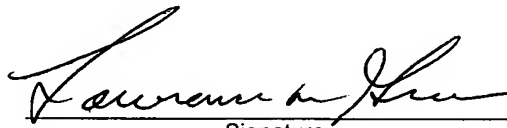
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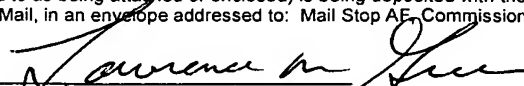
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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) B0884.70074US01	
	Application Number 10/777,342-Conf. #4933	Filed February 12, 2004	
	First Named Inventor Frederic Neftel et al.		
	Art Unit 3767	Examiner P. A. Gray	
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <p><input type="checkbox"/> applicant /inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>29,384</u></p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. _____</p> <p> Signature <u>Lawrence M. Green, Esq.</u> Typed or printed name <u>(617) 646-8000</u> Telephone number <u>Dec 22, 2006</u> Date</p> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>			

<input type="checkbox"/> *Total of _____ forms are submitted.

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DOCKET NO.: B0884.70074US01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Frederic Neftel
Serial No.: 10/777,342
Confirmation No.: 4933
Filed: February 12, 2004
For: MEDICAL DEVICE FOR INJECTING LIQUIDS

Examiner: Phillip A. Gray
Art Unit: 3767

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 22st day of December, 2006.

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Commissioner for Patents
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Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

The claims in this application stand rejected under 35 U.S.C. § 102. The rejection under 35 U.S.C. § 102 is appropriate for consideration under the Pre-Appeal Brief Conference Program, as established at 1296 *Off. Gaz. Pat. Office* 67 (July 12, 2005) because it is based on a clear error in applying the relevant law.

Rejection under 35 U.S.C. § 102

There is clear error in the final rejection of claims 1-24 under 35 U.S.C. § 102 because the law of inherency was incorrectly applied. Claims 1-24 were rejected under §102(b) as being anticipated by each of Heilman et al. (U.S. Patent No. 5,569,181), Lichtenstein (U.S. Patent No. 4,464,172), and Teirstein (U.S. Patent No. 5,533,978). It is well established that anticipation under §102 requires that each and every element as set forth in the claim is found, either expressly, or inherently in a single prior art reference. Applicant is requesting this review because not every element in the claims is found either expressly or inherently in any one of the applied references.

Claims 1-24 are directed to a method of injecting liquid under pressure to a patient. Unlike the prior art references, the inventive method uses a differential pressure to prevent upstream contamination. In this respect, even in the event that a valve fails, upstream contamination is still prevented due to the pressure difference between an intermediate pressure and a downstream pressure. Independent claim 1 specifically recites the step of closing the regulation system and the first occlusion system *to produce a greater intermediate pressure* than the downstream pressure whereby *the pressure difference between the intermediate pressure and the downstream pressure prevents the upstream flow of liquid after the injection has stopped*. Independent claim 15 recites the step of closing the regulation system to prevent liquid flow therethrough, and thereafter closing the first occlusion system *to produce a greater intermediate pressure* than the downstream pressure. Independent claim 18 recites the step of closing the regulation system and the first occlusion system *to maintain a greater intermediate pressure* than the downstream pressure *at least until the patient is disconnected from the tubing*.

Heilman is directed to an apparatus for delivering fluid to multiple patients, either sequentially or simultaneously. Lichtenstein discloses a computer-controlled device for performing diagnostic procedures such as blood sampling and injection of fluids into patients. Teirstein is directed to an apparatus for injecting radiographic dye during angioplasty.

There is no teaching or suggestion in any of these references to use a pressure difference to prevent upstream contamination as recited in independent claims 1, 15 and 18. This point appears to be conceded by the Examiner. In the Final Office Action dated September 6, 2006, it states "Concerning the amended limitation of the 'pressure difference between an intermediate pressure and the downstream pressure prevents the upstream flow of fluid after the injection has stopped' would be *inherent* in the prior art as a functional procedure that occurs as a result of the taught operation." (page 4 and 5, *emphasis added*). Although the Examiner is only referring to language in claim 1, Applicant presumes from the Office Action that the Examiner is also stating that a similar limitation in independent claim 15 and 18 regarding the pressure difference is also inherent in the prior art.

Law of Inherency

The devices described in Heilman, Lichtenstein and Teirstein each rely solely on mechanical structures to stop the flow of fluid. Some of the devices have a plurality of back-flow valves which operate in a series. Other devices interrupt the power supply to a pump and/or interrupt gravity flow to stop the flow of fluid. The references disclose increasing the

pressure in portions of the device with a pump, but this occurs only when injecting the fluid into the patient. There is no teaching or suggestion in any of the references to produce a greater intermediate pressure than the downstream pressure when injection to the patient is desired to be stopped, as recited in the claims. When injection is stopped, because the pump stops operating, the upstream or intermediate pressure decreases to that of the downstream pressure. Even if an operator could operate some of these devices to create an increased intermediate pressure with respect to the downstream nature after the pump stops (this is not clear, however) there is no teaching in any of these references to do so. Moreover, each of these references normally would be operated in such a fashion so that there would be no increased intermediate pressure. Certainly, operation of each device would not necessarily result in an increased intermediate pressure.

“In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis added). See MPEP §2112. The Examiner has not met this burden of providing a basis. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). “To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-1951 (Fed. Cir. 1999). See also MPEP §2112 IV. Because the devices described in Heilman, Lichtenstein and Teirstein do not necessarily perform the claimed methods, the Examiner incorrectly applied the law of inherency.

The Examiner’s actions are inconsistent with the Federal Circuit’s holding in *Electro Medical Systems, S.A. v. Cooper Life Sciences, Inc.* 34 F.3d 1048, 32 USPQ2d 1017 (Fed. Cir. 1994). In that case, Electro Medical Systems (EMS) argued that Cooper’s U.S. Patent No. 4,412,402 was anticipated by a prior art patent. The ‘402 patent is directed to a dental device for removing plaque and stains without damaging a tooth surface. The claim in question recites equipment for “effecting abrasion” by delivering a pressurized jet of gas laden with particles surrounded by “a substantially *unpressurized* flow of liquid as a continuous liquid curtain.” EMS argued that the claim was anticipated by the prior art patent which disclosed a “blasting and spraying gun,” contending that although the prior art patent showed a *pressurized* liquid, it could be set to be any water pressure and, therefore inherently

described the claimed invention. This argument was rejected by the Federal Circuit, which held that “The mere fact that a certain thing may result from a given set of circumstances is insufficient to prove anticipation...EMS was required to prove that an *unpressurized* flow is necessarily present in the [prior art patent], and that it would be so recognized by persons of ordinary skill.” *Id.* at 1052 (*emphasis added*).

The present claims are clearly patentable in light of *Electro Medical Systems*. In *Electro Medical Systems*, EMS asserted that a certain pressure configuration was inherent in a prior art patent that only disclosed a *pressurized* liquid, but that permitted operation at any pressure whereas the patent claimed an *upressurized* flow of liquid. Similarly, in the present application, the prior art patents disclose no increased intermediate pressure after injection is stopped, but could (arguably) be operated to produce an increased pressure. The pending claims, however, are directed to a method which involves producing a greater intermediate pressure than the downstream pressure. The mere fact that one could (perhaps) operate the prior art to meet the claim limitation is not enough to anticipate the claims, in the absence of a teaching to do so, or in the absence of a showing that the prior art necessarily operated in that fashion.

Accordingly, the Examiner clearly erred in concluding that the pending claims are anticipated by Heilman, Lichtenstein and Teirstein.

Transient Pressure Difference

During a telephone discussion with the Examiner on May 24, 2006, and again in the Final Office Action mailed September 6, 2006, the Examiner stated that he thought that the references may inherently disclose a transient pressure difference at the moment a valve is closed because of pressure created by a pump upstream. Without agreeing that there even would be a transient pressure difference in any of the cited references, Applicant believes that the pending claims also distinguish over a configuration in which a short term transient pressure difference exists momentarily after a valve is closed.

In the last Amendment, dated June 7, 2006, Applicant amended independent claim 1 to clarify that “the pressure difference between the intermediate pressure and the downstream pressure prevents the upstream flow of fluid after the injection has stopped”. This language was added to clearly distinguish over a device in which a transient pressure difference occurs when a valve is shut off. As set forth in greater detail in the Amendment, a transient pressure difference would quickly dissipate, such that this configuration would not prevent the upstream flow of liquid after the injection has stopped, as recited in claim 1.

Independent claim 15 was not amended, because Applicant believes that this claim also distinguishes over a device with a transient pressure difference. Claim 15 recites closing the regulation system and thereafter closing the first occlusion system to produce a greater intermediate pressure than the downstream pressure. Closing the first occlusion system after the regulation system would necessarily prevent any such transient pressure differential caused by the pump stopping after closing the first occlusion system. There is no teaching to operate any of the devices in this manner and this order of operation is not necessarily present in the prior art.

Independent claim 18 was added in the Amendment dated June 7, 2006, in an effort to address the Examiner's concern about transient pressure differences. In particular, claim 18 recites closing the regulation system and the first occlusion system to maintain a greater intermediate pressure than the downstream pressure at least until the patient is disconnected from the tubing. Even if a device were to produce a transient pressure difference at the moment a valve is closed, claim 18 still distinguishes over art that has a transient pressure difference because claim 18 recites that the greater pressure is maintained for a period of time, i.e. at least until the patient is disconnected from the tubing.

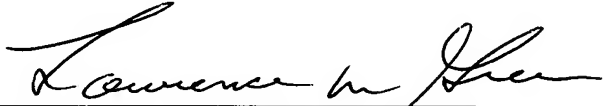
For these additional reasons, Applicant believes that the Examiner has clearly erred in rejecting all of the claims under 35 U.S.C. §102 and that the rejections should be withdrawn.

Conclusion

The rejection of claims 1-24 under 35 U.S.C. § 102 is clearly erroneous, and Applicant respectfully requests that the panel reverse the rejection.

Respectfully submitted,

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